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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/857,132	05/29/2001	Knut E. Rasmussen	01-11 US	9635

7590 01/27/2003

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[REDACTED] EXAMINER

PADMANABHAN, KARTIC

ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 01/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/857,132	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Kartic Padmanabhan	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 November 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-3 and 11-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-3 and 11-20 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-3 and 11-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 1-3 and 11-20 are rejected as vague and indefinite for the numerous recitations of "adapted" because it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchinson*, 69 USPQ 138.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Art Unit: 1641

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3 and 11-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasmussen et al. (WO 97/25606) in view of Berg (US Pat. 6,164,144).

Rasmussen et al. teach a device and method for liquid-liquid microextraction. The method comprises proving a carrier, modifying the carrier, immobilizing a solvent (acceptor solution) on the carrier surface, contacting the carrier with the sample (which may be in solution), concentrating and fixing the analyte of interest to the solvent, and analyzing the carrier. Preferably, a fiber is used as the carrier. The fibers for use with the invention may be made of porous polymers such as polyacrylate. The amount of solvent to be immobilized on the solvent is in the range of 1-5 ul (page 4). The carrier with immobilized solvent is inserted into the sample solution, where the pH may be altered to favor partitioning of analyte and solvent (page 5). In one embodiment, the fiber is withdrawn into the needle of a syringe, and the needle is used to penetrate the septum of a solvent vial, at which time the fiber is lowered and solvent is immobilized. The fiber is then withdrawn back into the needle and used to penetrate the sample vial. After the fiber is lowered into the vial, analytes are partitioned by agitating the vial (page 7). Since the fiber only accommodates 1-5 ul of sample, it is inherent that the sample vial has a

volume greater than 50X this amount. The sample solution for use with the invention may be plasma. However, the reference does not specifically teach the use of a hollow fiber, magnetic stirring bar, an acidified acceptor solution, or a sponge.

Berg teaches methods and device for solid phase microextraction (SPME). The reference discloses the use of a fiber with SPME, wherein the fiber acts as a "sponge". In addition, the reference also teaches the use of a magnetic stirring bar as the means of agitation of a sample in a vial.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use a magnetic stirring bar, a hollow fiber, and an acidified acceptor solution with the invention of Rasmussen et al. By using a hollow fiber, one would have been able to fill the fiber with acceptor solution rather than immobilizing the solution on the surface of the fiber. With such an arrangement, partitioning will occur between analyte and acceptor within the fiber, at which time acceptor solution with analyte can be removed and analyzed. One would have been able to use this arrangement with a reasonable expectation that it would provide results similar to those when acceptor is immobilized on the surface of the fiber. It would have further been obvious to use a magnetic bar as the stirring means to establish extraction equilibrium (partitioning between sample and acceptor) for the analyte because magnetic stirring bars are very well known in the art for use when agitation is necessary, as taught by Berg et al. One would have had a reasonable expectation of success in using a stirring bar as the agitation means with the method of Rasmussen et al. because both Berg and Rasmussen et al. are drawn to extraction methods and one would have recognized that any agitation means could have been used with the method and device of Rasmussen et al. Furthermore, it would have been obvious

Art Unit: 1641

to acidify the acceptor solution of Rasmussen et al. because Diazepam, the analyte of interest in Example 1, has its highest partition coefficient at an acidic pH. Finally, it would have also been obvious to modify the method and device of Rasmussen et al. by using a sponge instead of a fiber as the disposable container. Since Berg teaches that the fiber of the method acts as a sponge, one would have had a reasonable expectation of success in carrying out the method of Rasmussen et al. with the replacement of the fiber with a sponge material. In addition, although Berg deals with solid phase microextraction, the teaching of Berg would have been applicable to the modified method of Rasmussen et al. because Rasmussen et al. use a SPME fiber in their liquid-liquid microextraction method (page 10).

Response to Arguments

8. Applicant's arguments filed November 18, 2002 have been fully considered, but they are not persuasive.

9. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

10. In response to applicant's arguments that neither Berg nor Rasmussen teach the use of a hollow fiber or acidified acceptor solution in liquid-liquid microextraction or liquid-liquid-liquid microextraction, the examiner agrees. However, the combination of the references does indeed

Art Unit: 1641

teach this feature, for reasons discussed supra under 35 USC 103. Applicant further submits that claim 11, which recites the acidified acceptor solution is patentable because claim 15, on which claim 11 depends, is patentable. However, applicant has not provided any basis in this argument (page 23) for why claim 15 is patentable. Applicant goes on to argue that Rasmussen does not discloses all the aspects of the claims to qualify it as a proper 103 reference. Specifically, applicant contends that the reference does not teach an apparatus with first and second containers, wherein the second has permeable walls receives a specific volume ration of acceptor. The examiner agrees that this sole reference may indeed not teach every element of the pending claims. However, this is not required of a reference applied under 35 USC 103, as Berg is relied upon to cure the deficiencies in Rasmussen. If Rasmussen had independently taught each and every element of the pending claims, it would have been applied under 35 USC 102, rather than 103. It is noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

11. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, applicant is directed to the rejection under 35 USC 103 for a detailed

Art Unit: 1641

discussion of the reasons one of ordinary skill in the art would have been motivated to modify Rasmussen with the features taught by Berg. Applicant argues that the present invention is advantageous over Rasmussen because the reference requires an additional desorbing step. However, by using the hollow fiber taught by Berg, this desorbing step would prove unnecessary in the modified method of Rasmussen and Berg.

12. In response to applicant's argument that Berg is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Berg is directed to an extraction method, which is pertinent to the present invention, as well as to Rasmussen. The references, as well as the claimed invention, deal with extraction, with the difference being the mechanism with which the extraction is done. Berg is in now way relied upon for solid phase microextraction in any way, but rather for features pertinent to extraction in general.

Conclusion

Claims 1-3 and 11-20 are rejected.

Reference: Nyman et al. is cited as art of interest for teaching a method and apparatus for liquid extraction.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1641

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kartic Padmanabhan whose telephone number is 703-305-0509. The examiner can normally be reached on M-F (8:30-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 703-305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-5207 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Kartic Padmanabhan
Patent Examiner
Art Unit 1641


January 17, 2003


LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

1/24/03